

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application No.: 10/643,674
Filing Date: August 19, 2003
Applicant: Suong-Hyu Hyon, et al.
Group Art Unit: 1796
Examiner: Susan W. Berman
Title: ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE MOLDED
ARTICLE FOR ARTIFICIAL JOINTS AND METHOD OF PREPARING
THE SAME
Attorney Docket: 1736-000001/REB

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**APPEAL BRIEF UNDER 37 CFR § 41.37 AND REQUEST FOR FOUR-MONTH
EXTENSION OF TIME**

This is an appeal from the Office Action mailed October 28, 2008 (herein the "Final Action") and the subsequent Advisory Action mailed May 26, 2009, for which a Notice of Appeal and Pre-Brief Conference Request was filed on April 28, 2009. The Pre-Brief Appeal Conference Decision was issued May 26, 2009. This brief is timely filed on October 28, 2009, with a four-month extension of time. Accordingly, Applicants hereby request a four-month extension of the time for filing of this brief and have authorized the petition fee to be withdrawn from Deposit Account 08-0750.

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I. Real Party in Interest

The real parties in interest in the present application are Biomet Manufacturing Corp. and BMG Incorporated. BMG Incorporated is the sole owner and assignee of all rights in the invention. The assignment was recorded in the United States Patent and Trademark Office on May 6, 1996, at reel/frame: 008082/0009 (inventors to BMG Incorporated). Biomet Manufacturing Corp. is a subsidiary of Biomet Inc., and is the exclusive licensee of BMG Incorporated, the assignee of record.

II. Related Appeals and Interferences

An appeal was filed April 22, 2009 in related U.S. Application Serial No. 10/643,673, filed August 19, 2003 (Attorney Docket No. 1736-000001/REC). No decisions have been rendered in the Appeal. Both the '673 Application and the subject Application are divisional reissue applications of reissue Application Serial No. 10/141,374, filed May 8, 2002.

III. Status of the Claims

Claims 1-39, 42, 44, 54-83, 86, 88, 98, and 102-136 are cancelled. Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97, and 99-101 are currently pending and stand rejected in the application. This appeal is taken as to all of the rejected claims, i.e., Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97, and 99-101.

IV. Status of Amendments

All of the amendments have been entered in this application, including the Amendment After Final Pursuant to 37 CFR § 1.116, filed on April 28, 2009.

V. Summary of Claimed Subject Matter

Independent Claim 40 recites a method of making an ultra high molecular weight polyethylene (UHMWPE) block by first crosslinking a UHMWPE with high energy radiation (for example, gamma irradiation). After irradiation, the crosslinked UHMWPE is heated to a compression deformable temperature below the melting point, and subjected to pressure. The block is then allowed to cool. In certain embodiments, the block is allowed to cool while pressure is maintained to keep the deformed state.

Independent Claim 84 recites a method of making an artificial joint component for implantation based on the same steps of crosslinking, heating, subjecting to pressure, and cooling as in Claim 40. Claim 84 further recites the step of processing the cooled block to make the implant.

The main claims are mapped to the specification (37 CFR § 41.37(c)(v)) as follows:

Claim	Support in Specification
40. (amended) A method for producing an ultra high molecular weight polyethylene block, comprising: (a) <u>crosslinking</u> an ultra high molecular weight polyethylene block having a molecular weight not less than 5 million by irradiating the block with a high energy radiation at a level of at least 1 MR;	<p>The invention relates to an ultra high molecular weight polyethylene (UHMWPE) molded article for artificial joints ... Col. 2, lines 43-44.</p> <p>As the raw UHMWPE, one having a weight-average molecular weight of 2 to 8 million, preferably 5 to 7 million is used. Col. 3, lines 22-23.</p> <p>This UHMWPE molded article having molecular orientation or crystal orientation can be obtained by irradiating a low dose of a high energy ray to a raw UHMWPE molded article to introduce a very small amount of <u>crosslinking</u> points in polymer chains so as to be crosslinked slightly. Col. 2, lines 47-51.</p> <p>A preferable dose of irradiation (energy) is the dose to give the above-mentioned density of crosslinking and 0.01 to 5.0 MR, preferably 0.1 to 3 MR in case of radioactive rays. Col. 3, lines 62-65.</p>

<p>(b) heating said crosslinked block up to a <u>compression deformable temperature</u> below the melting point of the UHMWPE;</p> <p>(c) subjecting said heated block to <u>pressure</u>; and then</p> <p>(d) <u>cooling</u> said block.</p>	<p>Irradiated UHMWPE molded articles were obtained by compression-deforming and cooling naturally similarly in Preparation Example 1 except that a dose of irradiation of gamma-ray was changed to 1.0 MR, 1.5 MR or 2.0 MR. Col. 5, lines 43-46.</p> <p>Then, this slightly crosslinked UHMWPE molded article is heated up to a <u>compression-deformable temperature</u>. The compression-deformable temperature of is a temperature of around or not less than the melting point of the crosslinked UHMWPE, and is concretely <u>from the melting point minus 50° C to the melting point</u> plus 80°C. It is most suitable to heat up to a temperature of not less than the melting point, particularly preferably 160°C to 220°C, further preferably 180°C to 200°C to melt completely. The compression-deformation can be carried out, however, at a temperature of <u>even around the melting point, for example 100° to 130°C</u>. Col. 4, lines 4-14.</p> <p>The compression-deformation is carried out under a <u>pressure</u> of 30 to 200 kgf/cm.sup.2, usually 50 to 100 kgf/cm.sup.2, with heating at the above-mentioned temperature in a die suitable for the use or be using a hot press machine. Col. 4, lines 18-20.</p> <p>Then, the UHMWPE molded article having the molecular orientation or crystal orientation obtained by the compression-deformation as described above is <u>cooled</u> and solidified while keeping the deformed state. If the deformed state is set free before solidification, the stretched molecular chains are relaxed in stress to return to the <u>original state</u> ... Col. 4, lines 34-39.</p>
<p>84. (amended) A method for producing an ultra high molecular weight polyethylene artificial joint component for implantation in a human or other animal, comprising:</p>	<p>Same as Claim 40.</p>

(a) crosslinking an ultra high molecular weight polyethylene block having a molecular weight not less than 5 million by irradiating the block with a high energy radiation at a level of at least 1 MR;	Same as Claim 40.
(b) heating said crosslinked block up to a compression deformable temperature below the melting point of the UHMWPE;	Same as Claim 40.
(c) subjecting said heated block to pressure; then	Same as Claim 40.
(d) cooling said block; and	Same as Claim 40.
(e) processing said cooled block to form said component.	The compression-deformed molded article which is obtained as described above can also be processed to a socket for artificial joints by cutting and can be molded by means of the compression-deformation mold with a die comprising a convex and concave portions. Col. 5, lines 4-8.

VI. Grounds of Rejection to be Reviewed on Appeal

I. Whether Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97, and 99-101 are properly rejected under 35 U.S.C. § 251 as claiming subject matter surrendered during prosecution of the application for the patent upon which the present reissue is based.

II. Whether Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97, 100, and 101 are properly rejected under 35 U.S.C. § 103(a) as obvious from U.S. Patent No. 5,030,402, Zachariades, issued July 9, 1991 (herein "*Zachariades '402*") in view of U.S. Patent No. 3,886,056, Kitamaru et al., issued May 27, 1975 (herein "*Kitamaru*").

III. Whether Claim 99 is properly rejected under 35 U.S.C. § 103(a) as obvious from *Zachariades '402* in view of *Kitamaru*, and further in view of U.S. Patent No. 5,037,928, Li et al., issued August 6, 1991 (herein "*Li*").

VII. Arguments

I. The claims do not recapture surrendered subject matter.

All claims have been rejected under 35 U.S.C. § 251, as allegedly being an improper recapture of subject matter surrendered in the application for the patent (U.S. Patent No. 6,168,626, Hyon et al., issued January 2, 2001, herein referred to as "the '626 Patent") upon which the present reissue is based. Final Action, page 5. The rejection states, "The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. § 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application." *Id.*

Applicants submit that the appealed claims do not constitute an impermissible recapture of subject matter surrendered during prosecution of the ‘626 Patent, because they do not violate the fundamental principle on which the recapture rule is based – the current claims do not result from an attempt by the Applicants to re-prosecute the claimed subject matter of the ‘626 Patent. Rather, the current claims reflect prosecution of a patentably distinct invention that embodies claim limitations that are, in significant aspects, more narrow than the claims of the ‘626 Patent. As a result, the error upon which this reissue application is an error that can be corrected by reissue.

To review the law briefly, a reissue is available whenever any patent is, through error and without deceptive intention, deemed wholly or partly inoperative or invalid by reason of the patentee claiming more or less than he had a right to claim in the patent. 35 U.S.C. § 251. Furthermore, of particular relevance to the present case, the statute relevant to divisional applications is applicable to reissue applications. *Id.* It provides that when two or more “independent and distinct”¹ inventions are claimed in one (reissue) application, the Director may require restriction to one of the inventions. 35 U.S.C. § 121. Furthermore, a reissue patent can be granted enlarging the scope of the claims of the original patent if it is filed within two years from grant of the original. 35 U.S.C. § 251.

However, if the reissue claims are broader in any aspect than claims cancelled from the application during prosecution, the claims can run afoul of the recapture rule. The recapture rule is said to “prevent[] a patentee from gaining, through reissue, the subject matter that he surrendered in an effort to obtain allowance of the original claims.” *In re Clement*, 131 F.3d 1464, 45 U.S.P.Q.2d 1161, 1165 (Fed. Cir. 1997). The rule is grounded in the statutory requirement of error – the deliberate surrender of subject matter to obtain the allowance of claims over cited art is not the kind

¹ This statutory phrase is interpreted and applied by the Patent Office as though it read “independent or otherwise distinct.” See MPEP § 802.01.

of “error” that can be corrected by the reissue process. *Haliczer v. United States*, 356 F.2d 541, 545, 148 U.S.P.Q. 565, 569 (Ct. Cl. 1966). The recapture rule is also based on principles of equity and includes the concept of estoppel. *Ball Corp. v. United States*, 729 F.2d 1429, 1435, 221 U.S.P.Q. 289, 296 (Fed. Cir. 1984). (“The recapture rule is a creature of equity and it embodies ... estoppel notions...”). Indeed, the reissue statute itself is “based on fundamental principles of equity and fairness, and should be construed liberally.” *In re Weiler*, 790 F.2d 1576, 1579, 229 U.S.P.Q. 673, 675 (Fed. Cir. 1986) (internal citations omitted). The recapture rule is thus flexible and does not apply in every case where broadened claims are presented by reissue. See *Mentor Corp. v. Coloplast Inc.*, 998 F.2d 992, 996, 27 U.S.P.Q.2d 1521, 1525 (Fed. Cir. 1993) (“Reissue claims that are broader in certain respects and narrower in others may avoid the effect of the recapture rule.”)

Recapture is analyzed by a three-step process. *In re Clement*, supra. *Pannu v. Storz Instruments, Inc.*, 258 F.3d 1366, 59 U.S.P.Q.2d 1597 (Fed. Cir. 2001). As summarized in *Pannu*, the first step is to determine whether and in what aspect the claims are broader than the (original) patent claims. *Id.*, at 59 U.S.P.Q.2d 1600. The second is to determine whether the broader aspects relate to surrendered subject matter. *Id.* If there are no such broader aspects, then the recapture rule does not apply. But, if there are such broader aspects, the final step in the analysis is a determination of whether claims are materially narrowed in other respects to avoid the recapture prohibition. *Id.* In particular, as discussed further below, if the reissue claim is as broad as or broader in an aspect related to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim. *In re Clement*, 45 U.S.P.Q.2d at 1165.

Addressing the first two *Pannu* prongs in the Office Action, the Examiner laid out where certain aspects of the claims are allegedly broader than corresponding aspects of the claims in the ‘626 Patent, and documented instances during prosecution of the ‘626 Patent where such aspects

were amended or added leading to narrower claims and to “surrender” of subject matter. The Examiner then concludes that the reissue claims contain such broadening aspects and that the broadening aspects relate to surrendered subject matter. Without further analysis or consideration of the third prong of the *Pannu* analysis, the Examiner then reaches the ultimate conclusion that the reissue claims constitute an impermissible recapture, rejecting the claims accordingly.

As discussed below, the broadening aspects identified by the Examiner do not deprive the reissue claims of their materially narrowed aspects with respect to the issued patent claims. These aspects are, in fact, more significant than the broadening aspects identified in the prosecution history. Thus, following the *Pannu* analysis, the present claims are proper, and the rejection should be reversed, for either or both of two reasons.

- First, the present reissue claims were prosecuted for a different invention than that prosecuted in the ‘626 Patent, and have a broadening aspect never presented during prosecution of the ‘626 Patent, such that any other broadening aspects of the reissue claims do not relate to surrendered subject matter (*Pannu* second prong).
- Second, even if the present claims are viewed as having broadening aspects related to surrendered subject matter, they are materially narrowed in other aspects so as to avoid recapture (*Pannu* third prong).

A. *Pannu* Analysis Step 1 - Applicants’ claims (while ultimately not barred by the recapture doctrine) do present elements broader than elements present in claims of the ‘626 Patent.

In her analysis of the *Pannu* recapture rule, Examiner Berman identified aspects of the reissue claims that are allegedly broadened compared to the original patent claims. *See for example*, Final Action, page 6-7. Current Claim 40 and original patent Claim 3 (the only method claim of the ‘626 Patent) are set forth in the Table 1, below, for convenient reference.

Table 1

Comparison of Reissue Claims and Claims of the '626 Patent

Current Reissue Claim	Claim of '626 Patent
<p>40. A method for producing an ultra high molecular weight polyethylene block, comprising:</p> <p>(a) crosslinking an ultra high molecular weight polyethylene block having a molecular weight not less than 5 million by irradiating the block with a high energy radiation at a level of at least 1 MR;</p> <p>(b) heating said crosslinked block up to a compression deformable temperature below the melting point of the UHMWPE;</p> <p>(c) subjecting said heated block to pressure; and then</p> <p>(d) cooling said block.</p>	<p>3. A method for producing an ultra high molecular weight polyethylene molded block having orientation of crystal planes in a direction parallel to a compression plane, comprising</p> <p>slightly crosslinking an ultra high molecular weight polyethylene molded block having a molecular weight not less than 5 million by irradiating the block with a high energy ray and thereby introducing a very small amount of crosslinking points into molecular chains of the block, then</p> <p>heating the crosslinked ultra high molecular weight polyethylene molded block up to a compression deformable temperature,</p> <p>compression-deforming the block by compressing the block in a direction perpendicular to the compression plane so as to deform the block, and then</p> <p>cooling the block while keeping the block in a deformed state under pressure, said block after cooling having a thickness range of 5 to 10 mm in a direction perpendicular to the compression plane.</p>

Broadening aspects identified by Examiner Berman include the following.

1. The recitation of “block” is allegedly broader than “molded block having orientation ... compression plane ” set forth in the original claims.
2. The reissue claims are allegedly broader by failing to recite UHMWPE “having a molecular weight not less than 5 million.”
3. The reissue claims are allegedly broader by reciting “subjecting said block to pressure” instead of “compressing the block in a direction perpendicular to a compression plane so as to deform the block.”
4. The reissue claims are allegedly broader for omitting the recitation that “said block after cooling having a thickness range of 5 to 10 mm in a direction perpendicular to the compression plane.”
5. The reissue claims are allegedly broader for failing to recite “under pressure” in the phrase “keeping the block in a deformed state under pressure.”

As a preliminary matter, some of the allegedly broader aspects of the claims do not in fact give the claims a significantly broader scope than those of the ‘626 Patent. For example, the limitation of “compressing the block in a direction perpendicular to a compression plane so as to deform the block” is not significantly narrowing because the language merely defines a compression plane (i.e. all compression is in a direction perpendicular to such a plane), so that the limitation is in the claim whether or not literally recited. Likewise, keeping the block in a deformed state “under pressure” is not limiting because pressure must be applied to keep the deformed state, whether or not the limitation is literally recited. Nevertheless, for the purposes of this appeal, Applicants acknowledge that there are elements of the claims that are broader than corresponding elements in the claims of the ‘626 Patent. As further discussed below, however, these broadening

aspects do not represent an impermissible recapture of subject matter under either or both of the second and third prongs of the *Pannu* analysis.

B. *Pannu* Analysis Step 2 - While aspects of the claims correspond to aspects of the '626 Patent claims, they are not an attempt to recapture surrendered subject matter because the reissue claims are addressed to a distinct invention, having a significant broadening aspect never presented during prosecution of the '626 Patent.

After identifying aspects of the reissue claims that are allegedly broader than corresponding aspects of the '626 Patent claims, the Examiner then alleges instances during prosecution of the '626 Patent where such aspects were amended or added. These alleged instances are set forth below, with reference to the letters assigned by the Examiner for amendments filed during prosecution of the '626 Patent.

In Amendment F filed February 25, 1999, "molded article" was changed to read "molded block" to address a rejection over *Kitamaru* (U.S. Patent 3,886,056).

In Amendment B filed April 2, 1997, the phrase "molded article" was amended to "molded article having orientation of crystal planes" in part to overcome a rejection over U.S. Patent No. 5,030,487, Rosenzweig, issued July 9, 1991 (herein "*Rosenzweig*"). In Amendment C filed December 5, 1997, it was further amended to recite orientation of crystal planes "in a direction parallel to a compression plane" in response to a rejection over U.S. Patent No. 4,655,769, Zachariades, issued April 7, 1987 (herein "*Zachariades* '769").

The Examiner states the limitation "having a molecular weight not less than 5 million" was added in Amendment H filed May 4, 2000 to distinguish over *Kitamaru*.

The Examiner states the limitation "compressing the block in a direction perpendicular to a compression plane so as to deform the block" was added in Amendment D filed September 3, 1998 to resolve a rejection under 35 U.S.C. § 112.

The Examiner states the limitation reciting a thickness range of 5 to 10 mm was added in Amendment G filed September 10, 1999 in response to a rejection over *Kitamaru*.

Finally, the “under pressure” limitation is said to have been added in Amendment G to distinguish over *Kitamaru*.

While elements of the present reissue claims are, indeed, similar to claim elements presented during prosecution of the ‘626 Patent, the amendments and arguments regarding the issued claim elements are not relevant to the reissue claims because the reissue claims are directed to a distinct invention. When their initial reissue application (U.S. Application Serial No. 10/141,374, to which the present application claims priority), was filed on May 8, 2002, Applicants were not attempting to re-open prosecution to obtain by reissue what they could not obtain in the original patent. Rather, Applicants presented the issued claims, without amendment, along with 262 other claims that were significantly different from the issued claims, pursuing subject matter disclosed in their specification that was not pursued in prosecution of the ‘626 Patent. Insofar as these other reissue claims are broader in some aspects than the issued claims, such broadening is permitted under the reissue statute because they were on file within two years of issue of the parent.

The significant differences between the issued claims of the ‘626 Patent and the reissue claims were recognized in the restriction requirement issued in the parent to this application. Acknowledging the differences among the 273 claims presented in the initial ‘374 reissue application, the Examiner required restriction, concluding that the new reissue claims (i.e. the 262 claims presented in the reissue application other than the issued claims of the parent) were in fact independent and distinct from the claims of the ‘626 Patent. ‘374 Application, Office Action issued August 13, 2003 (herein the “Restriction Requirement”). Specifically, the issued claims of the ‘626 Patent (Claims 1 – 11), were classified in the Restriction Requirement as Invention I in class 264,

subclass 488. *Id.*, page 2. The other claims, including the claims leading to those currently on appeal, were classified in eleven total distinct and independent inventions.

The subject application was filed as a divisional of the '374 Application, consequent to the Restriction Requirement, presenting appealed Claims 40 and 84. Appealed Claim 40 is derived from Claim 40 of the '374 application, which the Examiner placed in Invention Group III (class 264, subclass 488). *Id.* Appealed Claim 84 is derived from 84 of the '374 application, which in turn was part of Invention Group V, class 264, subclass 488. Applying the Restriction Requirement, the Examiner concluded that Claims 1-11 (Group I) of the '626 Patent are unrelated to Claim 40 (Group III) and Claim 84 (Group V), stating

The method of Group I (claims 3-6) as claimed and the method of Group III as claimed set forth different modes of operation and would be expected to produce different products. The method of Group I (claims 3-6) as claimed and the method of Group V as claimed set forth different modes of operation and produce different products.

Id., at page 6. The differences between reissue Claims 40 and 84 of the '374 Application and Claim 3 (the relevant independent method claim) of the '626 Patent are illustrated in Table 2, below.

Table 2

Comparison of Reissue Claims as Filed with the '626 Patent

Reissue Claims Presented in the '374 Application	Issued Claim 3 from the '626 Patent
<p>40. A method for producing an ultra high molecular weight polyethylene block, comprising:</p> <p>(a) crosslinking an ultra high molecular weight polyethylene block having a molecular weight not less than 5 million by irradiating the block with a high energy radiation at a level of at least about 1 MR;</p> <p>(b) heating said crosslinked block up to a compression deformable temperature;</p> <p>(c) subjecting said heated block to pressure; and</p> <p>(d) cooling said block.</p>	<p>3. A method for producing an ultra high molecular weight polyethylene molded block having orientation of crystal planes in a direction parallel to a compression plane, comprising</p> <p>slightly crosslinking an ultra high molecular weight polyethylene molded block having a molecular weight not less than 5 million by irradiating the block with a high energy ray and thereby introducing a very small amount of crosslinking points into molecular chains of the block, then</p> <p>heating the crosslinked ultra high molecular weight polyethylene molded block up to a compression deformable temperature,</p> <p>compression-deforming the block by compressing the block in a direction perpendicular to the compression plane so as to deform the block, and then</p> <p>cooling the block</p> <p>while keeping the block in a deformed state under pressure, said block after cooling having a thickness range of 5 to 10 mm in a direction perpendicular to the compression plane.</p>
<p>84. A method for producing an ultra high molecular weight polyethylene artificial joint component for implantation in a human or other animal, comprising:</p>	<p>3. A method for producing an ultra high molecular weight polyethylene molded block having orientation of crystal planes in a direction parallel to a compression plane, comprising</p>

<p>(a) crosslinking an ultra high molecular weight polyethylene block having a molecular weight not less than 5 million by irradiating the block with a high energy radiation at a level of at least about 1 MR;</p> <p>(b) heating said crosslinked block up to a compression deformable temperature;</p> <p>(c) subjecting said heated block to pressure;</p> <p>(d) cooling said block; and</p> <p>(e) processing said block to form said component.</p>	<p>slightly crosslinking an ultra high molecular weight polyethylene molded block having a molecular weight not less than 5 million by irradiating the block with a high energy ray and thereby introducing a very small amount of crosslinking points into molecular chains of the block, then</p> <p>heating the crosslinked ultra high molecular weight polyethylene molded block up to a compression deformable temperature,</p> <p>compression-deforming the block by compressing the block in a direction perpendicular to the compression plane so as to deform the block, and then</p> <p>cooling the block</p> <p>while keeping the block in a deformed state under pressure, said block after cooling having a thickness range of 5 to 10 mm in a direction perpendicular to the compression plane.</p>
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Comparison of reissue Claims 40 and 84 reveals a significant omission from the reissue claims relative to the claims of the '626 Patent – the lack of the step of keeping the deformed state while cooling. (See element (d) of Claims 40 and 84.) Indeed, the Examiner's recapture analysis does not cite this aspect of the reissue claims as constituting recapture. This broadening aspect of the reissue claims cannot, in fact, constitute recapture, as cooling under pressure was required in the claims throughout prosecution of the '626 Patent. For reference, Claim 5 of the application for the

'626 Patent is set forth below, as filed. (Claim 5 was the broadest method claim filed in the application, from which issued Claim 3 was derived.)

5. (as filed, emphasis added) A method for producing an ultra high molecular weight polyethylene molded article having molecular orientation or crystal orientation, wherein

the ultra high molecular weight polyethylene molded article is crosslinked slightly by irradiating a high energy ray and introducing a very small amount of crosslinking points into molecular chains, and

the crosslinked ultra high molecular weight polyethylene molded article is compression deformed after heating up to a compression deformable temperature and then cooled with keeping the deformed state. As discussed above, this significant broadening of the claims is not alleged to relate to surrendered subject matter. This is, of course, because the requirement for deformation while cooling does not constitute subject matter "surrendered" during original prosecution -- keeping the deformed state was always present in the claims and was not added or amended during prosecution of Applicants' '626 Patent.

Accordingly, appealed Claims 40 and 84 are derived from reissue claims that were considered by the Examiner to be separate and distinct from the original patent claims, as having a significant broadening aspect that was never present in the claims of the '626 Patent as filed. The current claims do not represent an attempt to re-prosecute the claims pursued in the '626 Patent. Rather, they relate to a patentably distinct invention. Thus, the broadening aspects of the appealed claims do not relate to surrendered subject matter; the claims do not constitute an impermissible recapture under the second prong of the *Pannu* analysis.

C. Pannu Analysis Step 3 – Even if broadening aspects are deemed to be related to subject matter surrendered during prosecution of the ‘626 Patent, the reissue claims are materially narrowed in other aspects so as to avoid the recapture rule.

The present claims are also not barred by the recapture doctrine because, even if they are deemed to have broader aspects related to surrendered subject matter, they are materially narrowed in other aspects so as to avoid recapture. In particular, the claims are materially narrowed by reciting a compression deformation temperature below the melting point of the ultra high molecular weight polyethylene, while the original claims had no such limitation and encompassed deformation temperatures both above and below the melting point. As is further discussed below, this narrowing is significant from both a technical and patentability perspective -- technically, by focusing on compression of a material under temperature conditions below its melting point, rather than processes in which the compression may be performed on a melted material; and from a patentability perspective, by further distinguishing the literature of record considered during prosecution of the ‘626 Patent, as has been recognized by the Examiner. The reissue claims thus have a materially narrow aspect relative to the original claims, despite the presence of some broader aspects.

1. The narrowing aspects of Applicants’ reissue claims are significant, and impart a fundamental narrowness to the claims, in contrast with cases where recapture has been found.

A review of the leading cases reveals, not surprisingly, that the recapture analysis is highly dependent on the facts. The mere finding of a broadening aspect in reissue claims, even if ostensibly related to narrowing that occurred during prosecution of the issued patent, is not dispositive. Rather, consistent with the equitable underpinnings for reissues, the cases evidence a balancing of the statutory right to pursue broadened claims with the prohibition against re-opening

prosecution of an issued patent. Cf., *Mentor Corp. v. Coloplast, Inc.*, 27 U.S.P.Q.2d 1521; *In re Clement*, at 45 U.S.P.Q.2d 1166.

Nevertheless, while each case must be analyzed on its own, a review of the facts of some of the leading reported reissue cases can be instructive. Such an analysis leads to the conclusion that the present claims are not barred by the recapture doctrine, even if they have broader aspects related to surrendered subject matter, because they are materially narrowed in other aspects so as to avoid recapture.

In several cases, reissue claims have been found to be invalid as recapturing surrendered subject matter with impermissibly broadening claim elements, without any countervailing narrowing. All of these cases can be distinguished from the present case, however. In particular, in *Mentor Corp*, supra, the patentee for a condom catheter unsuccessfully argued that the reissue claims avoided the recapture rule on the basis that they contained added limitations that materially narrowed the claims. *Mentor*, at 27 U.S.P.Q.2d 1525. Instead, the Court found that “the added limitations do not narrow the claims in any material respect compared with their broadening.” *Id.* Specifically, an added recitation that the catheter material be “flexible” did not materially limit the scope of a claim that already recited the material was “resilient.” *Id.* Likewise, an added limitation that the catheter be rolled to form a “single” roll was not materially limiting where the catheter could only be rolled to form a single roll when connected to a urine collection means. *Id.* In the present case, by contrast, the focus on compression of a material under temperature conditions below its melting point required by the reissue claims is significantly more narrow than the issued patent claims, which subsume processes where compression is performed on a melted material. Applicants are not simply substituting one claim term with another similar or nominally different

term; the narrowing aspect of Applicants' claims constitutes a significant reduction in the scope of temperatures under which the claimed processes are performed.

In another case in which recapture was found, *Hester Industries v. Stein, Inc.*, 46 U.S.P.Q.2d 1641 (Fed. Cir. 1998), the Court also held that the reissue claims were not materially narrowed. The applicant for a high temperature steam cooker in *Hester* argued that the reissue claims were materially narrowed by the addition of the limitation of "high humidity steam" and a "spiral conveyance path." But the Court determined that "high humidity steam" was essentially the same scope as the limitation of the original claims that recited "at or near 100% humidity[,] 100 degrees C[,] and a pressure above atmospheric." Further, the added limitation of a "spiral conveyance path" was not materially limiting compared to the original "means passing said conveyor belt" because a spiral path was the only means described in the specification and the scope of the means-plus-function claim was thereby limited to the spiral path and equivalents. The Court held that these limitations were equal to or broader than the original claims, and were not materially narrowing limitations. *Id.*, at 1647, 1650. Again, by contrast, the temperature limitation in the present claims is significantly more narrow than in the issued patent claims and not a minor variation of a previously presented claim term.

In *In re Clement*, supra, the Court held that the reissue claims directed to a method of treating waste paper were barred by the recapture rule, as they were not materially narrowed. The reissue applicant broadened a multi-step process claim, eliminating the recitation of room temperature and specific energy limitations of a first step, and eliminating the high temperature, specific energy and pH values from the third and fourth steps. These limitations were added to distinguish the invention and overcome a prior art rejection. *Id.* As discussed further below, the *Clement* Court also analyzed the claims for aspects that were narrower than the issued claims and

not completely unrelated to rejections made during prosecution of the issued patent. The reissue claims were found to be narrower by reciting a brightness of “at least 59 ISO in the final pulp,” which the Court found was related to a prior art rejection in the issued patent *Id.*, at 1165. Nevertheless, the Court held that the reissue claim was “on balance” broader than narrower in a manner pertinent to the surrendered subject matter. *Id.*, at 1166. In the present case, by contrast, the temperature limitations added in the present claims are significant, both in a technical sense and in their relevance to the rejections made during prosecution of the ‘626 Patent (as will be discussed further below).

Finally, impermissible recapture was also found in *Pannu*, supra. The Court held that the reissue claims were not materially narrowed, and therefore presented recaptured surrendered subject matter. *Id.*, at 59 U.S.P.Q.2d 1601. The reissue claims, directed to intraocular lenses, omitted a limitation as to the shape of the lens haptics, which was added during prosecution of the original application to overcome a prior art rejection. The reissue claims were argued to be narrower with respect to snag resistant means, however, requiring the means to be “at least three times greater” than the width of the haptics, rather than “substantially greater” as in the issued patent claims. The reissue claims also required the snag resistant means to be “substantially coplanar” with the haptics. The *Pannu* Court held that the reissued claims were invalid under the recapture rule, finding that the reissued claims “were not narrowed in any material respect compared with their broadening.” *Id.* Unlike the present case, however, there was no suggestion in the analysis of *Pannu* that the size or orientation of snag resistant means had any relevance to a rejection made during prosecution of the issued patent, or that the limitations added to the claims were technically significant.

On the other hand, in *Ball*, supra, reissue claims directed to a dual slot antenna assembly were found to be materially narrowed so that they did not violate the recapture rule. The reissued

claim recited “a plurality of feedlines.” *Id.*, at 221 U.S.P.Q. 291-292. The cancelled claim recited “feed means includ[ing] at least one conductive lead.” The prosecution history showed that the patentee added the “plurality of feedlines” limitation in an effort to overcome prior art. *Id.* The reissue claim included limitations not present in the canceled claims that related to the feed means element, but allowed for multiple feedlines. The reissue claims were further narrowed by the recitation that the cavity element of the claims is filled with a dielectric material. *Id.*, at 221 U.S.P.Q. 295. On balance, the claim was found to be narrower than the canceled claim with respect to the feed means aspect. The Court allowed the reissue claim, stating that the “broader aspects of [the] reissue claims do not deprive them of their fundamental narrowness of scope relative to the canceled claims.” *Id.*, at 221 U.S.P.Q. 296.

As in *Ball*, and unlike the fact situations in *Mentor*, *Hester*, *Pannu* and *In re Clement*, the narrowing aspect of Applicants’ reissue claims – that the compression deformable temperature is below the melting point – significantly narrows the scope of the claims. Before the narrowing aspect is added, the canceled claims encompass methods in which compression is carried out at any compression deformable temperature, which according to the reissue specification is “concretely from the melting point minus 50°C to the melting point plus 80°C.” See ‘626 Patent, column 4 lines 8-9. The narrowing temperature limitation in the reissue claims removes more than half of the range of suitable temperatures encompassed by the original method claims canceled during prosecution. The difference in scope due to the narrowing limitation in the reissue claims is much greater than in, for example, *Mentor* (“flexible” not materially narrowing compared to “resilient”) or *Hester* (“high humidity steam” not materially narrowing relative to “at or near 100% humidity”). As in *Ball*, the broader aspects of Applicants’ reissue claims do not deprive them of a “fundamental narrowness” relative to the canceled claims.

2. Further, as articulated in *In re Clement*, the narrowing aspect of Applicants' claims is not "completely unrelated" to claim rejections made during prosecution of the '626 Patent, so that recapture does not bar the claims.

In *In re Clement*, 45 U.S.P.Q.2d 1161 (Fed. Circ. 1997), the Court elaborated on the determination of whether reissued claims are materially narrowed to avoid the recapture rule.

"If the reissue claims is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim...."

In re Clement, 45 U.S.P.Q.2d at 1165. The above statement of the rule necessarily implies that the recapture rule does not bar the claim if the reissue claim is narrower in an aspect that is not completely unrelated to the rejection. That is, to avoid the recapture rule, a narrowing aspect offered in a reissue claim must be somehow related to the rejection (and not "completely unrelated to the rejection"). The reissue claims are now discussed with these principles in mind.

As discussed above, Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97, and 99-101 embody a significant narrowing aspect relative to the issued claims of the '626 Patent -- the requirement that the compression deformable temperature is below the melting point of the UHMWPE. The narrowing aspect is not completely unrelated to claim rejections made during prosecution of '626 Patent. Indeed, as demonstrated below, had the recitation of a compression temperature below the melting point been presented by amendment during prosecution, the claims would have distinguished over the art applied during the prosecution of the '626 Patent. For this reason, the narrowing aspect is definitely related to the claim rejection, or at least is not "completely unrelated" to the rejection. As a result, the claims escape the recapture rule according to the analysis articulated in *Pannu* and *In re Clement*. The relationship of the limitations in the current claims to the prosecution of the parent claims is now discussed.

With reference to the amendments discussed by the Examiner in the Final Action and recited above, Amendment B, filed April 2, 1997 during prosecution of the '626 Patent, responded to rejection of the parent claims over *Rosenzweig* (U.S. Patent No. 5,030,487). In *Rosenzweig*, ultra high molecular weight polyethylene is expanded after crosslinking to make a heat shrink material that returns to its original shape upon heating. *Rosenzweig* does not suggest compression deforming a crosslinked polyethylene as in the rejected claims. In setting forth a 35 U.S.C. § 102 rejection in the Office Action issued December 2, 1996, the Examiner² cited *Rosenzweig*'s 230°C sintering step and subsequent cooling as anticipatory of the claims, but in the same sentence admitted that the steps are carried out prior to crosslinking. Because *Rosenzweig* admittedly did not disclose all the claim steps, the claims were patentable over *Rosenzweig* even without amendment. Further, had the claims at that time been amended to recite that the compression deformation was carried out at a temperature below the melting point, the claims would have further distinguished the reference. For this reason, the recitation that compression deformation is carried out below the melting temperature is not completely unrelated to the claim rejection — it is related to the claim rejection in that it would have led to a claim that distinguished over *Rosenzweig*.

In Amendment F, filed February 25, 1999, the claims were amended from "molded article" to a "molded block" in part to distinguish over *Kitamaru* (U.S. Patent No. 3,886,056), which disclosed fibers, films, and sheets. *Kitamaru* calls for making the fibers, films, and sheets, by heating ultra high molecular weight polyethylene above the melting point and applying pressure. The recitation of compression deformation at a temperature below the melting point would have distinguished the reference with or without the other amendments. Thus, the narrowing aspect of compression deformation below the melting temperature is not "completely unrelated" to the rejection.

² The Examiner for prosecution of the '626 Patent was a different Examiner than for the present reissue application.
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Similarly, in Amendment G, filed September 10, 1999, the parent claims were amended to recite a block having dimensions of 5 to 10 mm to distinguish over *Kitamaru*. But, as in Amendment F, an amendment at that time to recite a compression deformation temperature below the melting point of the polyethylene would have helped distinguish over the reference. For this reason, such a narrowing aspect offered in the reissued claims is not “completely unrelated” to the rejection.

In Amendment C, method Claim 5 was amended in the preamble to recite an article having orientation of crystal planes “in a direction parallel to a compression plane” in response to a rejection over *Zachariades '769*, and after an interview with the Examiner discussing the method claims and other rejected claims. It is not clear from the record what aspects of *Zachariades '769* formed the basis of the rejection. In the August 6, 1997 Office Action, the Examiner cited to Col. 5, lines 58-68 and Col. 8, lines 34-39 of *Zachariades '769* to support the rejection. Those passages are repeated here for convenience (emphasis added throughout):

As shown in FIG. 1, an UHMWPE pseudo-gel according to this invention may be prepared from a raw UHMWPE powder 20 by dissolving the UHMWPE in a solvent at 21, preferably a non-volatile solvent such as paraffin oil, in a temperature range from 140°-170° C., preferably in the high end of the temperature range in order to disrupt the thermally persistent extended chain morphology of the raw UHMWPE powder and decrease the number of nucleation sites which allow for the preparation, upon cooling, of large lamellar single crystals.

...

Thermal treatment may be brought about by heating the semicrystalline structure from a gel-like precursor to a temperature close to or above the melting point of the polymer and then cooling to ambient under modest compression (≤approximately 50 Atm). This treatment resulted in a significant porosity reduction.

Although the basis of the rejection is not completely clear, it is evident that it was somehow based on passages of the reference that referred to temperatures above the melting temperature of the UHMWPE, at least in preferred embodiments. Applicants submit that, had the claims recited or

been amended to recite the narrowing aspect of heating to a compression deformable temperature below the melting temperature, the claims would have further distinguished over the reference.

In Amendment D, method Claim 5 was further amended to recite the article is compressed “in a direction perpendicular to the compression plane” to overcome a formal objection remaining after the *Zachariades* ‘769 rejection was withdrawn following Amendment C. As discussed above, the limitation is not particularly narrowing because it merely makes explicit what is already inherently present -- that the compression plane is perpendicular to the direction of compression. In any event, since the narrowing aspect of the reissue claims is relevant to the *Zachariades* ‘769 rejection of Amendment C discussed above, Applicants submit the same recitation would have been relevant to Amendment D.

The relatedness of the narrowing aspect (deformable temperature below the melting point) to the claim rejections over *Kitamaru* is underscored by the course of prosecution of the claims in related reissue applications. Specifically, in reissue application Serial No. 10/643,673, filed August 19, 2003 (which is also a divisional of the initially filed ‘373 reissue application), Applicants presented claims directed to crosslinking a raw UHMWPE article slightly with low dose irradiation; heating the irradiated article; compression deforming the heated article; and then cooling the article while maintaining the deformed state. To address an art rejection over *Kitamaru* (discussed above with respect to Amendments F and G), Applicants amended the claims to require heating at a temperature less than the melting point. ‘373 Amendment filed December 3, 2007. In the Final Rejection issued December 12, 2008, the Examiner then removed the rejection, stating:

The rejection of claim 104, 109, 114, 149-152 and 154-157 as being anticipated by *Kitamaru* et al (3,886,056) is withdrawn. *Kitamaru* et al teach extending UHMWPE under pressure in the molten state, while the instantly claimed method is now limited to temperatures between 50°C lower than the melting point and the melting point of the UHMWPE.

This analysis substantiates Applicants' position in the present reissue that the narrowing aspect, i.e. limiting the temperature to the range below the melting point, is related to the claim rejection, and avoids the recapture rule according to the analysis of *In re Clement*. The pending reissue claims are now rejected based on *Kitamaru* as a secondary reference, as combined with *Zachariades '402*. Notably, *Zachariades '402* was not the basis of a rejection during prosecution of the '626 Patent, underscoring the significance of the narrowing aspect of the present claims relative to the prosecution of the '626 Patent. (The *Zachariades '402* Patent now used as a primary reference is different than U.S. Patent No. 4,655,768, which was issued to the same inventor and cited during prosecution of the '626 Patent.)

Likewise, during prosecution of the second related reissue application, the Examiner has endorsed the factual basis of Applicants' position regarding the relevance of narrowing temperature limitations to the rejections made during prosecution of the '626 Patent. Specifically, a recapture rejection essentially identical to that issued in the present case has been issued in reissue application Serial No. 11/522,504, filed September 15, 2006, which is also a divisional of the initially filed '373 reissue application. Applicants presented claims in the '504 application directed to methods for making an intermediate ultra high molecular weight polyethylene, by a process that comprises crosslinking, and heating "at a temperature from its melting point minus 50°C to its melting point." '504 Application, Amendment filed April 6, 2009. To overcome a recapture rejection, Applicants argued that the narrowing temperature aspect of the claims was related to the rejections made during prosecution of the '626 Patent, and would have further distinguished the instant claims from the cited references. In response to these arguments, the Examiner stated, "It is agreed that such limitations would have further distinguished the instant claims from the prior art" (referring to limitations added during prosecution to state the compression deformable temperature was below

the melting point). ‘504 Application, Office Action issued June 12, 2009, page 3. Admittedly, the Examiner then disagreed with applying the facts to the rule of *In re Clement* and rejected the argument for that reason. But the Examiner’s own analysis – both in the present application and in the related ‘504 Application – establishes that the narrowing aspect of Applicants’ reissue claims is related to (at least not completely unrelated to) the rejections made in the prosecution of ‘626 Patent.

Thus, Applicants’ reissue claims, while having elements arguably broader than corresponding elements in the ‘626 Patent claims, were presented in prosecution of a patentably distinct invention which presents a significant broadening aspect never presented during prosecution of the ‘626 Patent. The significance of this broadening aspect is evidenced by the restriction requirement issued in this application. It is manifest, then, that Applicants’ prosecution of these claims is not an attempt to recapture subject matter surrendered during prosecution of the ‘626 Patent. But even if broadening aspects of the current reissue claims are viewed to be related to subject matter surrendered during prosecution of the ‘626 Patent, the reissue claims have a fundamental narrow aspect relative to the claims of the ‘626 Patent, material at least to the extent that it would have overcome art rejections made during prosecution of the ‘626 Patent. Thus, the reissue claims do not violate the recapture rule. Applicants respectfully request the rejection be reversed.

II. Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97, 100, and 101 are non-obvious in view of the combined *Zachariades* ‘402 and *Kitamaru* references because there is no apparent reason to combine them as suggested in the Final Action, other than through the use of impermissible hindsight.

Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97, 100, and 101 are rejected under 35 U.S.C. § 103(a) as obvious over *Zachariades* ‘402 in view of *Kitamaru*. Independent Claims 40 and 84 both recite the steps of crosslinking ultra high molecular weight polyethylene, heating the crosslinked UHMWPE to a compression deformable temperature, applying pressure to deform it, and cooling

the deformed UHMWPE. Claim 84 recites a further step of processing the cooled block to make an artificial joint component. As discussed below, there is no apparent rationale for combining *Zachariades '402* with *Kitamaru*. Rather, the combination is made only with impermissible hindsight.

Novel subject matter in a claim is patentable unless the subject matter as a whole would have been obvious to a person having ordinary skill in the art. 35 U.S.C. § 103. The Supreme Court most recently interpreted this statutory provision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007). Rejecting an overly rigid application of the traditional teaching-suggestion-motivation test, the *KSR* Court nevertheless confirmed the requirement that a motivation or apparent reason must be given for combining references. *Id.*, at 82 U.S.P.Q.2d 1396. A combination is not obvious if the art “teaches away” from making the combination. *Id.* at 1395.

The Supreme Court explicitly upheld the prohibition against improper hindsight reasoning. *Id.* at 1397 (“A fact finder should be aware ... of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning”) (internal citations omitted). See *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 1998) (“Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.”). See also *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) (“One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”). A motivation to combine is still required, but “the motivation to combine references can not come from the invention itself.” *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068, 1072, 30 U.S.P.Q.2d 1377, 1380 (Fed. Cir. 1993).

In brief, the primary reference, *Zachariades '402*, discloses solid state deformation of ultra high molecular weight polyethylene. *Zachariades '402*, at col. 1, lines 9-13. A product is made by compression molding UHMWPE at the melting temperature or below. *Id.*, at col. 3, lines 25-44. The UHMWPE is not crosslinked before molding. (See *Zachariades '402*, at col. 3, lines 10-25 stating the UHMWPE is "linear" with a finite molecular weight, indicating an uncrosslinked polymer, and see also col. 4, lines 11-17 stating that the deformed UHMWPE can be radiation crosslinked after processing if desired). Deformation is carried out simultaneously with shaping to the final product. *Id.*, at col. 3, lines 37-44. *Zachariades '402* suggests possible post-forming processes, after deformation, "such as cross-linking radiation." *Id.* at col. 4, lines 11-18. As relevant to all of the claims, *Zachariades '402* does not disclose the step of crosslinking UHMWPE before compression deformation. And, as relevant to independent Claim 84, the reference does not disclose the step of further processing the cooled article to form a component.

Kitamaru discloses extension of a crosslinked polyethylene (see *Kitamaru*, Abstract), while in *Zachariades '402* the polymer is compressed and molded. In *Kitamaru*, the extension is carried out at a temperature above the melting point of the polyethylene (*Id.*, at col. 3, lines 13-20), while in *Zachariades '402* compression is carried out in the solid state (below the melting point).

A. Independent Claims 40 and 84 are not rendered obvious by a proper combination of *Zachariades '402* and *Kitamaru*.

The Final Rejection attempts to reach the subject matter of the claims by (1) combining two references dealing with fundamentally different material technologies, (2) combining them in a fashion inconsistent with the process taught by the primary reference, and (3) arbitrarily selecting only certain features of the secondary reference for the combination. This combination represents an improper reconstruction of the references, guided only by impermissible hindsight use of Applicants' disclosure.

First of all, one of ordinary skill in the art would not combine the teachings of *Zachariades '402* and *Kitamaru* because they are drawn to significantly different materials. *Zachariades '402* produces thick polyethylene articles such as orthopaedic prostheses (e.g. acetabular liners and tibial plates). *Zachariades '402*, at col. 2, lines 47-50. *Kitamaru*, on the other hand, is concerned with polyethylene in the form of “fiber, film, and sheet” (*Kitamaru*, at col. 2, line 44), in the context of improved properties such as melting point and transparency, e.g., for bottles and containers (*Id.*, at col. 1, lines 28-35). *Zachariades '402* concerns molded products (*Zachariades '402*, col. 1, lines 812) while *Kitamaru* describes thin sheets and films such as those made compressing a 1.5 mm film at a 10:1 ratio (*Kitamaru*, Example 1). The *Kitamaru* films have improved transparency (*Kitamaru*, at col. 1, lines 5-9), while the *Zachariades '402* molded products have enhanced mechanical properties (*Zachariades '402*, at col. 1, lines 8-12). Because of these material differences, there is no motivation or apparent reason for a person of ordinary skill in the art to look to the secondary reference or to select features for combination with the primary reference.

Furthermore, the combination of references urged by the Examiner is, in fact, inconsistent with the teachings of *Zachariades '402*. *Zachariades '402* teaches crosslinking the UHMWPE after molding. *Zachariades '402*, at col. 4, lines 11-17. Given this teaching, a person of ordinary skill would not change the process of *Zachariades '402* to crosslink at the beginning of the process, as would be necessary to reach the subject matter of the claims. For this reason alone, a *prima facie* case of obviousness is not made out, and the rejection should be reversed.

Finally, the rejection reflects an arbitrary selection of one of the features of *Kitamaru* to combine with *Zachariades '402* – a selection made contrary to the teaching of *Zachariades '402* to make materially different products – while ignoring other features of *Kitamaru*. In particular, the Final Action arrives at the subject matter of the claims by selectively choosing the “crosslinking

before extending” feature of *Kitamaru* for combining with the *Zachariades* ‘402. But if another feature of *Kitamaru* -- application of pressure at a temperature above the melting point -- were instead arbitrarily selected and combined with *Zachariades* ‘402, one of ordinary skill in the art would not be led to Applicants’ claimed subject matter. Such a combination would lack entirely any teaching of a crosslinked polyethylene. And, of course, one would not arrive at Applicants’ invention if *Zachariades* ‘402 were to be modified with both features of *Kitamaru*.

The Final Action provides no rationale why just one of the features of *Kitamaru* is to be combined with *Zachariades* ‘402, but not the other (or for that matter, why not both). The Final Action provides no rationale why one of ordinary skill in the art would look to a reference that is focused on making transparent films and fibers to modify a process for making implants. And, the Final Action provides no rationale why one of ordinary skill in the art would modify the primary reference in a way contrary to its own teachings. Applicants submit the rationale for this combination is unintentionally but nonetheless impermissibly “based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” *ATD Corp*, supra. Because of this, a proper *prima facie* case of obviousness is not supported, and the rejection under 35 U.S.C. § 103(a) should be reversed.

B. Dependent Claim 84 recites a step of making a final product, further distinguishing it from *Zachariades* ‘402.

Claim 84 is non-obvious for the further reason that the combined references do not contain a teaching or suggestion of further processing to make a final product after deforming and cooling the UHMWPE. The disclosure of *Zachariades* ‘402 is strictly limited to molding directly into a final shape without further processing. *Zachariades* ‘402, at col. 3, lines 43-44 (“the product is simultaneously shaped into the final product”). *Kitamaru* does not make up for the deficiency. It is drawn mainly to the production of fibers and films (*Kitamaru*, at col. 3 lines 13-25), which do not

require further processing after deformation and cooling. Because the claim limitation of further processing to make a component is missing from the references, a *prima facie* case of obviousness is not made out as to Claim 84.

The other rejected claims are dependent either from Claim 40 or from Claim 84. They are patentable over the art or record because the claims from which they depend are patentable.

Accordingly, for all of the reasons discussed above, Applicants respectfully request that the rejection of the claims under 35 U.S.C. §103(a) be reversed.

III. Claim 99 is also not obvious from *Zachariades '402* and *Kitamaru*, and *Li* does nothing to remedy the deficiencies of those references.

Claim 99 is rejected under 35 U.S.C. §103(a) as being unpatentable over *Zachariades '402* in view of *Kitamaru*, and further in view of *Li* (U.S. Patent No. 5,037,928). Claim 99 is dependent on Claim 84, which is discussed above. Claim 99 further requires cutting the block to form a component.

The deficiencies of *Zachariades '402* and *Kitamaru* are discussed above regarding Claims 40, 84 and the other dependent claims. These references cannot be properly combined to teach the processes of Applicants' invention, which include the steps of crosslinking ultra high molecular weight polyethylene, heating the crosslinked UHMWPE to a compression deformable temperature, applying pressure to deform it, and cooling the deformed UHMWPE. Claim 84, upon which Claim 99 depends, is further distinguished from *Zachariades '402* because of its requirement that a final product is made after processing. Claim 99 (which is not subject to the rejection based solely on the combination of *Zachariades '402* and *Kitamaru*), is even further distinguished, by requiring cutting of the processed UHMWPE.

Li does not overcome the deficiencies of *Zachariades '402* and *Kitamaru* discussed above. *Li* discloses a process of making UHMWPE in the form of a shaped article. *Li*, col 1, lines 20-21. After forming, the article is heated, pressurized and slowly cooled without re-melting. *Li*, col. 1, line 43 - col. 3, line 20. In a passage cited by the Examiner, Example 5 of *Li* discloses cutting a formed UHMWPE rod to make test pieces. This teaching provides no apparent reason to for modifying *Zachariades '402* and *Kitamaru* to reach the subject matter of Claim 99. For these reasons, Applicants respectfully request that the rejection of Claim 99 under 35 U.S.C. §103(a) be reversed.

VIII. Conclusion - The claims do not recapture surrendered subject matter and are not obvious.

As discussed above, while the appealed claims present elements arguably broader than corresponding elements in the claims of the '626 Patent, they avoid the prohibition against recapturing surrendered subject matter. In particular,

- the appealed claims are not an attempt to re-prosecute the claims of the '626 Patent, but instead result from prosecution of a patentably distinct invention that embodies a significant broadening aspect never presented during prosecution of the '626 Patent, as evidenced by the restriction requirement issued in this application; and
- the appealed claims have a fundamentally narrow aspect relative to the claims of the '626 Patent, which is technically significant and related to rejections made during prosecution of the '626 Patent.

Therefore the appealed claims are not properly rejected under 35 U.S.C. § 251.

Further, the appealed claims are not obvious from the art forming the basis for the rejections under 35 U.S.C. 103(a). The rejections improperly

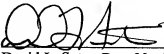
- combine two references dealing with fundamentally different material technologies;
- combine the references in a fashion inconsistent with the process taught by the primary reference; and
- arbitrarily select only certain features of the secondary reference for combination with the primary reference.

This combination represents an improper reconstruction of the references, guided only by impermissible hindsight use of Applicants' disclosure. Thus, the invention of Applicants' claims is patentably distinguishable over the art cited by the Examiner, and the rejection under 35 U.S.C. §103(a) is improper.

Accordingly, Applicants respectfully request that the Board reverse the rejections of Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97, and 99-101 under 35 U.S.C. §251 and 35 U.S.C. §103(a).

Respectfully submitted,

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Claims Appendix

Claims 1-39. Cancelled

40. A method for producing an ultra high molecular weight polyethylene block, comprising:

- (a) crosslinking an ultra high molecular weight polyethylene block having a molecular weight not less than 5 million by irradiating the block with a high energy radiation at a level of at least 1 MR;
- (b) heating said crosslinked block up to a compression deformable temperature below the melting point of the UHMWPE;
- (c) subjecting said heated block to pressure; and then
- (d) cooling said block.

41. A method for producing an ultra high molecular weight polyethylene block according to Claim 40, wherein said irradiation is gamma irradiation at a level of from 1 MR to 5 MR.

Claim 42. Cancelled

43. A method for producing an ultra high molecular weight polyethylene block according to Claim 42, wherein said heating is in a range of from 50°C lower than the melting temperature of the crosslinked ultra high molecular weight polyethylene to the melting temperature.

Claim 44. Cancelled

45. A method for producing an ultra high molecular weight polyethylene block according to Claim 40, wherein said pressure is applied so as to deform the block.

46. A method for producing an ultra high molecular weight polyethylene block according to Claim 45, wherein said deformation is in a direction perpendicular to the plane of compression.

47. A method for producing an ultra high molecular weight polyethylene block according to Claim 46, wherein said block is cooled in a compression-deformed state under pressure.

48. A method for producing an ultra high molecular weight polyethylene block according to Claim 47, wherein said block has an orientation of crystal planes in a direction parallel to the compression plane.

49. A method for producing an ultra high molecular weight polyethylene block according to Claim 46, wherein said block, after compression, has a thickness of at least 5 mm in a direction perpendicular to the compression plane.

50. A method for producing an ultra high molecular weight polyethylene block according to Claim 46, wherein said block, prior to compression, has a thickness of at least 3 cm.

51. A method for producing an ultra high molecular weight polyethylene block according to Claim 46, wherein said cooled block has a melting point of from 135°C to 155°C.

52. A method of producing an ultra high molecular weight polyethylene block according to Claim 40, wherein after said subjecting to pressure step, said block is subjected to isothermal crystallization.

53. A method for producing an ultra high molecular weight polyethylene block according to Claim 40, wherein after said subjecting to pressure step, said block is subjected to isothermal treatment at a temperature of from 100°C to 130°C for a period of from 1 hour to 20 hours.

Claims 54-83. (Cancelled)

84. A method for producing an ultra high molecular weight polyethylene artificial joint component for implantation in a human or other animal, comprising:

- (a) crosslinking an ultra high molecular weight polyethylene block having a molecular weight not less than 5 million by irradiating the block with a high energy radiation at a level of at least 1 MR;
- (b) heating said crosslinked block up to a compression deformable temperature below the melting point of the UHMWPE;
- (c) subjecting said heated block to pressure; then
- (d) cooling said block; and
- (e) processing said cooled block to form said component.

85. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 84, wherein said irradiation is gamma irradiation at a level of from 1 MR to 5 MR.

Claim 86. (Cancelled)

87. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 86, wherein said heating is in a range of from 50°C lower than the melting temperature of the crosslinked ultra high molecular weight polyethylene to the melting temperature.

Claim 88. (Cancelled)

89. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 84, wherein said pressure is applied so as to deform the block.

90. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 89, wherein said deformation is in a direction perpendicular to the plane of compression.

91. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 90, wherein said block is cooled in a compression-deformed state under pressure.

92. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 91, wherein said block has an orientation of crystal planes in a direction parallel to the compression plane.

93. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 90, wherein said block has a thickness, after compression, of at least 5 mm in a direction perpendicular to the compression plane.

94. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 90, wherein said block, prior to compression, has a thickness of at least 3 cm.

95. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 92, wherein said cooled block has a melting point of from 135°C to 155°C.

96. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 84, wherein said irradiation is conducted in the presence of oxygen.

97. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 84, wherein said irradiation is conducted under a vacuum or in an inert atmosphere.

Claim 98. (Cancelled)

99. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 84, additionally comprising processing said block, after cooling, by a process comprising cutting said block to form said component.

100. A method of producing an ultra high molecular weight polyethylene artificial joint component according to Claim 84, wherein after said subjecting to pressure step, said block is subjected to isothermal crystallization.

101. A method for producing an ultra high molecular weight polyethylene artificial joint component according to Claim 84, wherein after said subjecting to pressure step, said block is subjected to isothermal treatment at a temperature of from around 100°C to 130°C for a period of from 1 hour to 20 hours.

Claims 102-136. (Cancelled)

Evidence Appendix

None

Related Proceedings Appendix

None

Note: An appeal was filed April 22, 2009 in related U.S. Application Serial No. 10/643,673, filed August 19, 2003 (Attorney Docket No. 1736-000001/REC). No decisions have been rendered in the Appeal. Both the '673 Application and the subject Application are divisional reissue applications of reissue Application Serial No. 10/141,374, filed May 8, 2002.